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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,063	09/10/2003	Mitchell P. Fink	UPITT-008XX	3827
207	7590	10/19/2005	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,063

Applicant(s)

FINK ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 08/02/05.

The amendment filed 08/02/05 affects the application, 10/659,063 as follows:

Claim 1 has been amended. Claims 9-13 are withdrawn. Claims 1-6 and 8, the invention of Group I are prosecuted by the examiner. Applicant's arguments and amendments, see Remarks, pages 4-7, filed 08/02/05, with respect to claims 1-6 and 8 have been fully considered and are persuasive. The 112 rejections of claims said claims have been withdrawn. However, upon further consideration the following rejection is contained herein below.

Claims 1-6, 8-13 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Lund et al. (US 2002/0127646 A1)

In claim 1, the applicant claims "A method for treating of an inflammatory condition, said method comprising the steps of: providing a patient having an inflammatory condition; and administering to said patient a therapeutically effective amount of a composition comprising cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative thereof, in a form that is accessible to a receptor molecule, conveyed in a pharmaceutically acceptable carrier vehicle, wherein said composition reduces the degree of said inflammatory condition in

Art Unit: 1623

said patient.” Claims 2-6 and 8 are drawn to said method involving specific inflammatory conditions, specific routes of administration and the use of specific functional analogs, derivative of cADPR.

Lund et al. disclose that modulators, such as agonists and antagonists, of CD38 enzyme activity and/or modulators of cADPR dependent calcium responses and chemotaxis can be used in the treatment of disorders including inflammation in a subject (see page 4, 2nd col. paragraph [0032]). Furthermore, Lund et al. disclose examples of said antagonists (modulators) of cADPR which are cADPR derivatives and include, 8-NH₂-cADPR, 8-Br-cADPR, 8-CH₃-cADPR, 8-OCH₃-cADPR and 7-Deaza-8-Br-cADPR (see page 11, 1st col., paragraph [0099]).

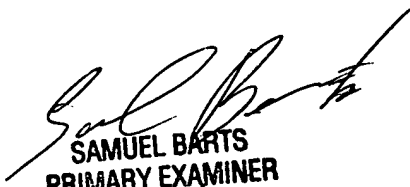
The difference between applicant's claimed method and the method disclosed by Lund et al. is that Lund et al. do not exemplify the use of a cADPR derivative to treat inflammation in a subject. However, Lund et al. teach that antagonists (modulators) of cADPR such as a cADPR derivative can be used to treat inflammation in a subject (see page 4, 2nd col. paragraph [0032] and see page 11, 1st col., paragraph [0099]).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Lund et al. to treat inflammation in a subject by administering to said subject a cADPR derivative, based on need, since Lund et al. teach that antagonists (modulators) of cADPR such as a cADPR derivatives can be used to treat inflammation in a subject.

One having ordinary skill in the art would have been motivated in view of Lund et al. to treat inflammation in a subject by administering to said subject a cADPR derivative, based on need, since Lund et al. teach that antagonists (modulators) of cADPR such as cADPR derivatives

Art Unit: 1623

can be used to treat inflammation in a subject. It should be noted that the administration via specific routes is common and obvious in the art and it is obvious to use any derivative, since Lund et al. disclose that cAPDR derivatives can be used.


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